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Tsutomu Okada

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EXAMINER

HUPCZEY, JR, RONALD JAMES

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3739

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/823,814	Applicant(s) OKADA, TSUTOMU	
	Examiner RONALD HUPCZEY, JR	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-10,15,17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7-10,15,17 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendments and arguments, received on October 14th, 2010, have been fully considered by the examiner. Currently, claims 1, 7-10 and 15 and 17-18 are pending with claims 1 and 17 amended. Applicant's amendment to claim 1 to state that the plurality of openings are rectangular is being considered supported by Applicant's figures 7A and 7B which should a generally rectangular shaped openings at reference character **33**. Applicant's amendment to claim 17 has partially obviated the previously filed rejection of claims 17 and 18 under 35 U.S.C. 112 1st paragraph and will addressed below. The following is a complete response to the October 14th, 2010 communication.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 17-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 17, the claim first recites "a plurality of triangular openings extending outward from the slide hole, an inner end portion of each triangular opening being coupled to the slide hole" in lines 15-16 on page 4 and goes on to further state (per the amendment) "wherein a triangular aperture into which the rod-shaped electrode ... and parts of said triangular aperture

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other than that part which is occupied by the rod-shaped electrode portion form opening, individually". The Examiner has carefully considered both the first and second portion of this recitation as well as the subject matter of the remainder of the claim in light of the specification. The Examiner **takes no issue** with the language added by the October 14th amendment. The added language is substantially the same to the recitation found on page 22 of the Specification discussing the structure of the embodiment in figures 8A and 8B. The Examiner **does take issue** with the limitation appearing in lines 15-16 on page 6. As was stated in the Non-final rejection of July 14th, 2010, the specification clearly sets forth on page 22 that "a triangular aperture 43 into which the rod-shaped electrode portion 41 is inserted for advance and retreat is formed in the distal end of a sheath 2. As shown in FIG. 8B, the aperture 43 is a triangular hole in which the rod-shaped electrode portion 41 is inscribed, as showing in FIG. 8B. The other parts of the aperture 43 than that which is occupied by the electrode portion 41 form openings 44, individually". From this recitation it can be seen that there is only a single triangular opening in the distal end of the sheath which, due to the passing of the electrode therethrough, creates three openings in the remaining space not occupied by the electrode. Unlike the embodiment depicted in Figures 7A and 7B, there clearly is no separate slide hole (as indicated as slide aperture 18 in figures 7A and 7B) from which additional openings of channels extend therefrom (as indicated by channels 33 in figures 7A and 7B) but rather, a single triangular aperture 43 as set forth on pages 22-23 of the specification. As such, it is the remains the Examiner's position that such a recitation as in lines 15-16 on page 6 is not supported by the specification and/or the drawings.

Claim 18 is rejected due to its dependency on claim 17. Appropriate correction is required. It is suggested by the Examiner that Applicant remove the above at-issue claim

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language in order to place claim 17 in better condition for consideration. Specifically, the Examiner believes that the remaining recitation in lines 18-22 on page 6 is fully descriptive of the structure depicted in figures 8A and 8B. It is further noted that the Examiner has indicated that the recitation in lines 18-22 is taken as fully supported by the specification and/or the drawings.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 17, the Examiner's believes that the recitation found in lines 15-22 on page 6 is unclear, rendering the scope of the claim unascertainable. Specifically, lines 15-16 recite "a plurality of triangular openings" and "each of the triangular openings" and lines 21-22 state that "parts of said triangular aperture other than that part which is occupied by the rod-shaped electrode portion form openings, individually" therein. At issue is if the "triangular openings" of lines 15-16 are the same as or different from the "openings" of line 22. Since it appears to the Examiner that the two portions of the last paragraph of the claim are defining the same structure in two different ways, is it the Examiner's position that sufficient clarification of the claim language is required. Claim 18 is rejected due to its dependency on claim 17.

Appropriate correction is required. It is suggested by the Examiner, as previously mentioned above, that Applicant remove the above at-issue claim language (of lines 15-16 on page 6) in order to place claim 17 in better condition for consideration and enhance the clarity. Specifically,

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the Examiner believes that the remaining recitation in lines 18-22 on page 6 is fully descriptive of the structure depicted in figures 8A and 8B. It is further noted that the Examiner has indicated that the recitation in lines 18-22 is taken as fully supported by the specification and/or the drawings.

Claim Rejections - 35 USC § 103

6. Claims 1 and 7-9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kokai (Pub. No. 4-329944) in view of Rexroth et al (hereinafter "Rexroth") (US Pat. No. 4,943,290).

Regarding claim 1, Kokai discloses a radio knife (electrosurgical device **1**) containing an electrically insulating sheath (insulating flexible tube **2**) having one flow channel inside (see channel in Figure 1), a distal end portion and a proximal end portion, the distal end portion of the sheath having a distal opening (tip opening **13**) and an axis, a support member (stopper member **4**) which closes the distal opening of the sheath (see Figure 4), the support member having a slide hole with a diameter smaller than that of the distal opening extending along the axis thereof (see Figures 1 and 4); an operating wire (operation wire **14**) axially moveable in the sheath (see paragraph [0013], lines 4-6), the rod-shaped portion being passed through the slide hole for axial projection and retraction (movement represented by **X**, see Figure 5); a control section (operation part **3**, operation handle **15**) which is provided on the proximal end portion of the sheath (see Figure 5) and controls the operating wire to project and retract the electrode portion in the axial direction (see paragraph [0013], lines 8-14), the control section having a high-frequency current supply portion (see paragraph [0010], lines 6-8) which supplies high-frequency current to the electrode portion (see paragraph [0011], lines 9-12), a liquid feed portion (cock **17**) which is

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provided on the proximal end side of the sheath and feeds liquid through the one flow channel inside the sheath towards the distal opening (see paragraph [0014]) and an opening for liquid feed which is formed in the support member, the opening being arranged around the slide hole (see paragraph [0014], line 3-5), communicating to the one flow channel (see Figure 1 and paragraph [0014]) and partially blocking flow in the vicinity of the distal end portion (see Figure 1). Kokai fails to disclose the inclusion of a plurality of rectangular openings extending outward from the slide hole with an inner portion of each of the rectangular openings being coupled to the slide hole and is silent in regard to the conductivity properties of the support member.

Rexroth discloses an electrosurgical device (electrosurgical apparatus **10**) containing an electrically insulating sheath (duct means **70**, see col. 9; 3-5) having a distal end portion and proximal end portion, the distal end portion of the sheath having a distal opening and an axis (see Figure 4). Rexroth further discloses the insulation sheath to inherently form a support member which closes the distal opening of the sheath and is insulating. The insulating tip defines a slide hole for the rod-shaped electrode shaft (electrode shaft **50**), the slide hole having a diameter smaller than that of the distal opening (see Figure 14). Additionally, Rexroth discloses the device to have a liquid feed portion (input fluid port **18**) and a plurality of straight openings (see openings of channels **75-78** extending in a straight manner into the duct means **70**, Figure 6) for liquid feed (see col. 8; 62 – col. 9; 8) extending outward from the slide hole (opening as in figure 6 extending from electrode shaft **50** outwardly to the inner portion of the means **70**) wherein an inner portion of each of the straight openings is coupled to the slide hole (portion of each of openings of channels **75-78** coupled to electrode shaft **50**) and the plurality of openings are set to a dimension at the point where each opening couples to the slide hole such that each cannot be

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penetrated by the electrode portion (support walls **80-83** converging to define the openings with channels **75-78** and dimensioned such that electrode shaft **50** cannot penetrate into the opening, see structural relationship in figure 6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a plurality of openings such as those disclosed by Rexroth in conjunction with the device disclosed by Kokai to provide an electrosurgical device with a plurality of straight openings extending outwardly from and coupled to the slide hole. As disclosed by Rexroth, it is old and well known to provide a plurality of openings for liquid to flow from in order to create a superior flow pattern to the proximity of the electrode tip. Furthermore, it would have been obvious to provide for an electrically insulative support member as discloses by Rexroth to the device of Kokai to prevent the short circuiting of the device.

Rexroth fails to specifically recite the claimed rectangular shape of the plurality of openings or that an entire width of each rectangular opening is set to a dimension such that it cannot be penetrated by the electrode portion. However, Rexroth does contemplate two different shaped and arranged sets of openings (as shown in figures 6 and 14) and discloses that the arrangement of the openings is provided to obtain a superior flow pattern which allows for the displacement of fluid and debris from the surgical site proximate the tip of the device. The walls **80-83** in figure 6 of Rexroth are also clearly defined as forms such that the electrode **50** is supported by the walls and as can be seen from figure 6, due to the relative size of the electrode rod **50**, the electrode rod **50** is prevented from penetrating into the openings. In light of the desire in Rexroth to provide a superior flow pattern and the contemplation of at least two design choices to provide such a flow pattern, it is the Examiner's position that it would have been

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obvious to one of ordinary skill in the art at the time the invention was made to provide each of the channels **75-78** of Rexroth as utilized in the combination above in the shape of a rectangular with a width over its entirety set to a dimension such that it cannot be penetrated by the electrode portion. Additionally, it is the Examiner's position that it would have been an obvious matter of design choice to rectangular openings as claimed in place of the shape of the channels in Rexroth, since applicant has not disclosed that this rectangular shape and set width solve any stated problem or is for any particular purpose other than that which is already addressed in Rexroth (i.e. preventing penetration by the electrode into the channels, supporting the electrode) and it appears that the invention would perform equally well with the channel shapes as provided in Rexroth. Furthermore, *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) addresses changes in shape of features of a claimed invention and states "The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant". In the instant case, no persuasive evidence and/or argument has been formally submitted in an affidavit or declaration which states on the record that the shape of the channel is significant and that such a modification would be non-obvious to one of ordinary skill in the art.

Regarding claims 7 and 15, Kokai discloses the sheath to have an extending portion extending ahead of the support member wherein the extending portion has an internal space which stores the electrode portion (see Figure 5).

Regarding claims 8 and 9, Kokai fails to disclose an extending portion location on the distal end portion of the rod-shaped portion and extending across the extending direction of the

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rod-shaped portion and for the extending portion to be a hooked bent portion extending substantially at right angles to the distal end portion. Rexroth discloses the electrode portion (electrode shaft **50**) to contain an extending portion (ball tip **26**) located on the distal end portion of the rod-shaped portion and extending across the extending direction of the rod-shaped portion (see Figure 15). Rexroth further discloses the extending portion to be a hooked bent portion (electrode tip **26C**) extending at substantially right angles to the distal end portion (see Figure 18). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Kokai with the electrode tip designs disclosed by Rexroth in order to catch tissue around the extending portion.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kokai (Pub. No. 4-329944) in view of Rexroth et al (US Pat. No. 4,943,290) as applied to claim 8 above, and further in view of Kittur et al (US Pat. No. 5,846,241).

Both Kokai and Rexroth fail to disclose the inclusion of a plate-like electrode at the distal end portion. Kittur et al discloses a radio knife (electrocautery device **10**) containing an extending portion (moveable head **22**) in a plate-like arrangement (second electrode **24**) coupled to the distal end of the rod-shaped portion (second wire **20**). Kittur further displays the portion to have a triangular shape (see shape of moveable head **22** in figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a plate-like electrode as disclosed by Kittur et al to the joint device of Kokai and Rexroth. All three device disclosed are directed toward the same field of endeavor and the utilization of a triangular plate-like electrode would increase the versatility of the device, effectively allowing it to successfully perform a wider variety of treatments.

Response to Arguments

8. Applicant's arguments filed October 14th, 2010 have been fully considered but they are not persuasive.

In response to Applicant's argument on page 6 of the Remarks that the amendments to claim 17 obviate the previously filed rejection of claims 17-18 under 35 U.S.C. 112, 1st paragraph, the Examiner respectfully disagrees. While Applicant has cancelled a portion of the previously at-issue language in claim 17, the Examiner still takes issue with the language found in lines 15-16. The rejection of claim 17 above states:

The Examiner **does take issue** with the limitation appearing in lines 15-16 on page 6. As was stated in the Non-final rejection of July 14th, 2010, the specification clearly sets forth on page 22 that "a triangular aperture 43 into which the rod-shaped electrode portion 41 is inserted for advance and retreat is formed in the distal end of a sheath 2. As shown in FIG. 8B, the aperture 43 is a triangular hole in which the rod-shaped electrode portion 41 is inscribed, as showing in FIG. 8B. The other parts of the aperture 43 than that which is occupied by the electrode portion 41 form openings 44, individually". From this recitation it can be seen that there is only a single triangular opening in the distal end of the sheath which, due to the passing of the electrode therethrough, creates three openings in the remaining space not occupied by the electrode. Unlike the embodiment depicted in Figures 7A and 7B, there clearly is no separate slide hole (as indicated as slide aperture 18 in figures 7A and 7B) from which additional openings of channels extend therefrom (as indicated by channels 33 in figures 7A and 7B) but rather, a single triangular aperture 43 as set forth on pages 22-23 of the specification. As such, it is the remains the Examiner's position that such a recitation as in lines 15-16 on page 6 is not supported by the specification and/or the drawings.

It is for at least this reasoning that the Examiner believes the language of lines 15-16 in claim 17 is not supported and still necessitates a rejection under 35 U.S.C. 112, 1st paragraph. It is also the Examiner's position that the rejection above clearly outlines the position of the Office and is fully response to Applicant's Remarks. Applicant is invited to contact the Examiner if further clarification is needed or to discuss this issue.

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9. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection. Specifically, Applicant has amended claim 1 to state that the plurality of openings are "rectangular" in shape and not "straight" as previously claimed. Additionally, Applicant now requires the openings to have an entire width set to a dimension such that it cannot be penetrated by the electrode portion. This amended claim language has necessitated the new interpretation of the Rexroth reference and the new grounds of rejection set forth above. It is the Examiner's position that even though Rexroth does not specifically disclose the shape and dimension of each of the plurality of openings as disclosed, it would have been a matter of obvious design choice to one of ordinary skill in the art to provide such a shape and dimension to each in light of the desire of Rexroth to provide a superior flow pattern near the tip of the electrode/device. It is also the Examiner's position that Applicant has not formally set forth on the record any significance to such a shape that would render such a modification as non-obvious. While Applicant has argued on page 9 of the Remarks that such a dimension for the entire width prevents penetration by the electrode portion even if the rectangular openings are worn, the Examiner takes such a statement, without evidence or support, as a mere allegation that the walls (and material of the walls) of Rexroth would wear away. Rexroth is clearly concerned with the supporting of the electrode rod **50** by the walls which form the channels and one would be reasonably expected to believe that the walls (and material) of Rexroth would provide the disclosed support throughout the useful lifetime of the device. It is for at least this reasoning and the grounds set forth in the rejection above that the Examiner believes a rejection of claim 1 as unpatentable over Kokai in view of Rexroth remains tenable. Applicant is invited to contact the Examiner to discuss the rejection or if further clarification is needed.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUPCZEY, JR whose telephone number is (571)270-5534. The examiner can normally be reached on Monday - Friday, 9 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ronald J. Hupczey/
Examiner, Art Unit 3739

/Michael Peffley/
Primary Examiner, Art Unit 3739

RJH